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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,725	01/27/2006	Hideki Tanji	10921.0296USWO	9962
52835	7590	05/13/2008		
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER TURK, NEIL N	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 05/13/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,725	<b>Applicant(s)</b> TANJI, HIDEKI	
	<b>Examiner</b> NEIL TURK	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### **Remarks**

This Office Action fully acknowledges Applicant's remarks filed on February 25<sup>th</sup>, 2008. Claims 1-13 are pending. Claims 14-18 have been cancelled. Any objection/rejection not repeated herein has been withdrawn by the Office.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 25<sup>th</sup>, 2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-13** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the amended recitation in claims 1 and 6 to, "...by making a correction to account for fluctuations of measurement wavelength of the irradiate light." The claims do not recite a step of

applying differing (varying) wavelengths as irradiating light and the light irradiator of the device is not recited as providing differing (varying) wavelengths for irradiating the reaction system and reference board. The claims have not made clear that the irradiating is done at multiple wavelengths (nor that the light source provides such a spectrum or multiple wavelengths). The claims have not made clear that the measuring is done at multiple wavelengths. The claims have also not made clear what causes fluctuations of measurement wavelength. Clarification is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-13** are rejected under 35 U.S.C. 102(b) as being anticipated by Matzinger (5,780,304).

Matzinger discloses a method and apparatus for analyte detection having an on-strip standard. Matzinger discloses that the invention relates to a test device and method for optically measuring the concentration of glucose in whole blood (lines 8-12, col. 1). Matzinger discloses a test strip that has a reaction zone (with color-producing reagent), which varies in reflectance as a function of the quantity of analyte present, and a standard zone that is positioned so as to lead the reaction zone as the strip is inserted into a reading apparatus. Matzinger discloses that the apparatus has optical means for

sequentially determining the reflectance value of the standard zone and for determining the reflectance value of the reaction zone after the strip has been inserted. The apparatus further includes means for calculating the presence and/or quantity of the analyte as a function of the standard zone and reaction zone reflectance (abstract; lines 26-60, col. 4; lines 61-67, col. 8; lines 1-31, col. 9). Matzinger discloses the apparatus 12 is provided with a power switch 20 for activating the apparatus and the optics block 32 is affixed to the apparatus and operable to direct light through aperture 30 in rapid bursts, "chops", for a period of time each time it is activated (lines 50-67, col. 5; lines 19-35, col. 6, figs. 1-3). Matzinger discloses that the standard zone 60 provides a calibrated standard reflectance value against which the reflectance of the color-developed reaction zone may be measured so as to allow computation and reporting of the presence or quantity of the analyte (lines 40-67, col. 9; lines 1-21, col. 10; lines 6-28, col. 11; figs. 1, 4, and 6). Matzinger also discloses that the reflectance of the surface presented to the optics is measured at all the various positions and multiple readings are taken at each position in spaced periods of time (lines 30-67, col. 11, figs. 7-11). Matzinger further discloses that the apparatus views the gray target and read a value for its reflectance at each LED wavelength and compare the values to the factory stored values for the gray reading. If there is a difference between the stored readings and the actual readings an adjustment is made (lines 36-50, col. 6; lines 5-67, col. 13). Matzinger discloses further calibration measures and checks throughout column 14. Matzinger also discloses that the microprocessor employs a look-up table to provide proper coefficients for calibration of the specific test strip employed in the apparatus to correct K/S ratio (lines 1-60, col.

15). Examiner interprets the function of the microprocessor to check and compare the gray readings against factory-stored values for adjustments to correspond to the selector and calculation corrections as claimed.

### ***Response to Arguments***

Applicant's arguments filed February 25<sup>th</sup>, 2008 have been fully considered but they are not persuasive.

**With regards to claims 1-13** rejected under 35 USC 102(b) as being anticipated by Matzinger et al. (5,780,304), Applicant traverses the rejection.

Applicant argues that Matzinger does not disclose or suggest a second detection step for irradiating light onto a reference board to detect a response from the reference board. Examiner argues that Matzinger discloses optical means that sequentially determine the reflectance value of the standard zone 60 (reference board) as well as the reaction zone, after the strip has been inserted. Thereby the optical means applies the second detection step of irradiating light on the standard zone to get a response from the standard zone. Examiner asserts that the recitation, "...the response from the reference board varying continuously with varying wavelength of the irradiated light" is not drawn to any active step in the method, but is recited as an inherent function of any reference board (material).

Applicant further argues that Matzinger does not disclose or suggest a calculation step for calculating a concentration of a specific component base on the first and second detection results by making a correction to account for fluctuations of

measurement wavelength of the irradiated light. Examiner argues that Applicant has not recited any step(s) of irradiating the system or reference board with different or varying wavelengths, and as discussed above, the claims are indefinitely recited in this respect. Examiner argues that Matzinger discloses means for calculating the presence and/or quantity of the analyte as a function of both the standard zone reflectance (1<sup>st</sup> detection result) and standard zone reflectance (2nd detection result) (abstract; cols. 9-11).

With respect to the device of claims 6-13, Applicant argues that Matzinger does not disclose the features. As discussed above, Applicant does not require different (varying) wavelengths of light to irradiate the reference board, and is thereby recited as an inherent function of any reference board (material). Further, Applicant argues that Matzinger does not disclose or suggest a detecting unit that detects a second response from the reference board. Examiner asserts that Matzinger discloses a photodetector 38 within optics block 32 for such detection. Examiner asserts that the response from any reference board will vary continuously with varying wavelength of irradiate light. Applicant also argues that Matzinger does not disclose or suggest a calculator connected to the detecting unit for calculating a concentration of a specific component of the sample based on the first and second responses by making a correction to account for fluctuations of measurement wavelength. As discussed above, the claims are indefinitely recited and unclear with respect to this recitation. Examiner argues that Matzinger discloses means for calculating the presence and/or quantity of the analyte as a function of both the standard zone reflectance (1<sup>st</sup> detection result) and standard



zone reflectance (2nd detection result) (abstract; cols. 9-11). Examiner further argues that the recitation, "by making a correction to account for fluctuations of measurement wavelength of the irradiated light" does not add to the calculating unit recited as the light irradiator has not been recited for such different (varying) wavelengths of irradiating light.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/

Supervisory Patent Examiner, Art Unit 1797

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